

Consolidated Risk Assessment Report of Monsanto Philippines, Inc.'s corn MON89034 x NK603 Application for Direct Use as Food, Feed or for Processing (FFP)

STRP, BPI-PPSSD AND BAI ASSESSMENT

Gene Interaction

MON 89034 x NK603 contains cry1A.105 gene encoding Cry1A.105 protein, cry2Ab2 gene encoding Cry2Ab2 protein and *cp4 epsps* gene encoding CP4 EPSPS protein. These proteins have different mode of actions and metabolic pathways and are not likely to interact to produce any known mammalian allergen or toxin. Cry1A.105 protein is likely to accumulate in the cytoplasm of corn cells while the Cry2Ab2 protein is expected to accumulate in the chloroplast of corn cells.

This is because the gene construct encoding Cry1A.105 does not include a sequence for targeting its transport to a specific sub-cellular location (organelle) and would thus accumulate in the cytoplasm of corn cells. The Cry2b2 protein is targeted to the plastids by the addition of a chloroplast transit peptide [CTP]. CP4 EPSPS is targeted to accumulate in the chloroplast. This protein belongs to the family of EPSPS synthases, which are enzymes involved in the penultimate step of the biochemical shikimic acid pathway producing aromatic amino acids in the chloroplasts of the plants.

Metabolic Pathways

The CP4 EPSPS protein belongs to the family of EPSP synthases, which are enzymes involved in the penultimate step of the biochemical shikimic acid pathway producing aromatic amino acids in the chloroplasts of plants. The gene, *cp4 epsps*, was derived from the *Agrobacterium* sp. strain CP4, a common soil-borne bacterium. CP4 EPSPS enzyme is far less sensitive to the inhibitory effects of glyphosate, hence conferring tolerance of the transgenic plants to glyphosate AIS-FRA-18-17 CORN MON 87427 x MON 89034 x MIR162 x NK603Cry1A.105 and Cry1Ab2 are insect control proteins and act through a toxic action in the gut of specific lepidopteran insects.

The Cry1A.105 and cry2Ab2 genes were derived from the common soil bacterium *Bacillus thuringiensis* (Bt) subsp. *kurstaki*. Heterologous-competition assays showed a common binding site for toxins belonging to the Cry2A family, which is not shared by Cry1A proteins which indicates a different mode of action for each protein.

Based on the documents provided by the developer, there is no possible unexpected effect of the stacked genes on the metabolism of the plant. This was being supported by weight of evidences encompassing the distinct mode of action of introduced proteins and the protein expression analysis. Each single event has been shown to be equivalent to conventional maize and each protein is not designed to alter the maize plant metabolism.

Since each protein has a different mode of action, interaction within these separate, distinct enzymatic activities and pathways is not expected, nor is a plausible mechanism of such interaction hypothesized. In accordance with this, the protein expression analysis showed that Cry1A.105, Cry2Ab2, and CP4 EPSPS proteins were expressed properly in the combined trait product MON 89034 x NK603 indicating that the inserted genes, cry1A.105, cry2Ab2, and cp4 epsps, are inherited and functioning properly when combined into the breeding stack. Thus, production of the Cry1A.105, Cry2Ab2, and CP4 EPSPS proteins in the stacked trait product do not produce any adverse effects on plant metabolism.

Gene Expression

The expression levels of Cry1A.105, Cry2Ab2 and CP4 EPSPS proteins in MON 89034 x NK603 were determined through Enzyme-linked Immunosorbent Assay [ELISA]. Results of the analysis indicated that the levels of expression of the proteins in MON 89034 x NK603 are equivalent to the corresponding single events, MON 89034 and NK603. Data on the expression level of the novel proteins in each corresponding single events and the combined trait product indicated that the proteins are expressed at low levels in MON 89034 x NK603.

The distinct mode of action of the novel proteins indicates that the presence of these proteins will not interact to produce any known mammalian allergen or toxins. The protein expression analysis showed that the inserted genes are inherited and functioning properly when combined into the breeding stack. Combined with the distinct modes of action of the proteins, the result supports conclusion that there is no change in introduced trait or interaction among the combined traits in MON 89034 x NK603.

Conclusion

After a thorough and scientific evaluation of the documents provided by Monsanto Philippines Inc. and other related literatures, scientific evidence indicates that the Combined Trait Product, N|ON 89034 x NK603 applied for direct use as food and feed or for processing has no evidence of interaction on the resulting gene products and as safe as it's conventional counterpart.

DENR RECOMMENDATION

Upon extensive review and evaluation of the application for direct use as food and feed or for processing, including the scientific evidences from provided references, literature and other studies the DENR-BC finds that the regulated article is safe as its conventional counterpart and is not expected to pose any significant risk to the environment.

DOH RECOMMENDATION

After a thorough and scientific evaluation of the documents provided by the applicant in support for their application for a biosafety permit for direct use as food and feed or for processing, the DOH-BC finds that the regulated article is as safe as its conventional counterpart and shall not pose any significant risk to human health and the environment. The regulated article does not require changes in the usual practices in unloading, and loading, hauling transport, storage and processing.

SEC RECOMMENDATION

The SEC Expert has stated that the GM product is not expected to drastically affect the current patterns of production, consumption, utilization, and trade since it has been introduced in the Philippines for more than fifteen years and has been adopted nationwide. After a thorough and scientific evaluation of the documents provided by the applicant for the application for direct use as food and feed or for processing of soybean MON87769 x MON 89788, the SEC Expert recommends for the approval and issuance of biosafety permit for the said GM product.